REMARKS/ARGUMENTS

This Amendment responds to the August 12, 2004 Office Action (the "Office Action") in the above referenced patent application.

Claims 73-86 remain in this application. Claims 73, 81, 83 and 84 have been amended. Claims 74 and 82 have been cancelled.

1 Enablement under 35 USC § 112, First Paragraph

The Examiner rejected claims 73-86 under 35 USC § 112, first paragraph, based on the contention that these claims lack enablement, though the Examiner conceded that the specification is enabling for opioid-oligomer conjugates of SEQ ID NOS: 1 or 48, as drawn to the broad formula of claim 1.

Applicants maintain that the previous claims as previously submitted are allowable; however, in order to expedite allowance of the application, applicants have elected to amend base claim 73 to recite a "therapeutic compound comprising an enkephalin compound." This reduces the number of potential combinations to a number that is well within the standard for satisfying the enablement requirement.

For a specification to be properly enabling under 35 USC § 112, first paragraph, it must (1) enable a person skilled in the art to use the invention as broadly as it is claimed (2) without undue experimentation.[1] The instant application is replete with examples that show how to make and use various enkephalin compounds, and "is primarily and illustratively directed to the use of enkephalin as a peptide component in various compositions and formulations of the invention."[2] Enkephalins are a discrete and well-defined class of peptides, and one skilled in the art would be able without undue experimentation, based on the teachings found in the specification, to make and use the present invention as broadly as it is claimed.

"Section 112 requires only an objective enablement; the invention needs to be sufficiently disclosed through illustrative examples or terminology to teach those of ordinary skill in the art how to make and

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[1] 35 U.S.C. 112; In re Goodman, 11 F.3d 1046, 1050 (Fed. Cir. 1993).
[2] Page 24, lines 10-11.

how to use the invention as broadly as it is claimed."[3] As the Examiner has already noted in the Office Action, the specification is enabled for SEQ ID NO: 1 and SEQ ID NO:48. Based on the objective enablement provided by the applicants for the conjugates of SEQ ID NOS: 1 and 48, it would only be a small step, without a need for undue experimentation, for one skilled in the art to use the teachings in this application to make and use the invention as broadly as it is claimed. With respect to various enkephalin compounds, the applicants have shown how to make the enkephalin compounds and how to test and use the same.

For the foregoing reasons, the applicants contend that the 35 USC § 112, first paragraph, rejection has been overcome, and that the claims are in condition for allowance.

2 Definiteness under 35 USC § 112, Second Paragraph

In the Office Action, the Examiner indicated that Claims 73-86 were rejected under 35 USC § 112, second paragraph, based on the contention that these claims are indefinite due to their breadth. The Examiner contends that it is unclear what the invention is, based on the claim language to any therapeutic compound with the broad oligomer formula of claim 73. Applicants maintain that the previous claims as previously submitted are allowable; however, in order to expedite the allowance of the application, applicants have amended base claim 73 to recite "a therapeutic compound comprising an enkephalin compound," in lieu of "a therapeutic compound," within the broad oligomer formula of claim 73.

A claim is indefinite only where a skilled artisan would not understand the claim when read in light of the specification.[4] Upon reading the specification in this application, one skilled in the art would readily appreciate and understand the definiteness of the unamended claims, and therefore there is no doubt that one skilled in the art would find the claims, as presently amended, to be definite.

For the foregoing reasons, the applicants contend that the 35 USC § 112, second paragraph, rejection has been overcome, and that the claims are in condition for allowance.

3 Amendment of Claims 83 and 84

The phrase "or an analog thereof" recited in Claims 83 and 84 finds support in the specification at page 7, lines 9-11; page 7, lines 24-26; page 9, lines 13-16; and page 13, lines 14-15.

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[3] *Musco Corporation v. Qualite, Inc.*, 41 U.S.P.Q.2d 195 (Fed. Cir. 1997).
[4] *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed.Cir. 1986).

CONCLUSION

Based on the amendments and arguments presented above, the pending claims are now in condition for allowance. If the Examiner has any questions about the present Amendment, a telephone interview is requested.

No fee is believed to be due at this time. Nonetheless, if it is determined that any fee or charge is properly payable in connection with the entry of this Amendment, the U.S. Patent Office is hereby authorized to be charged such fee to Deposit Account No. 13-4365.

Respectfully submitted,

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